

## Safety and Efficacy Programs

**W**uXi AppTec's orthobiologic program is designed to address your safety concerns while exploring additional considerations for product use. With exceptional expertise based on many years of testing experience, WuXi AppTec offers orthopedic medical device manufacturers a comprehensive program of safety and efficacy implant studies, including the most common models: critical size defect, drill defect, segmental defect and spinal fusion.

WuXi AppTec is a global leader in providing discovery, testing and manufacturing services for the pharmaceutical, biotechnology and medical device industries. Research-driven and customer-focused, with operations in China and the U.S., WuXi AppTec offers a broad and integrated portfolio of services designed to assist our customers with cost-effective and efficient outsourcing solutions.

### Safety and Efficacy Study Experience

Experienced in pilot, acute and chronic implant studies, including the following:

- Critical size defect  
*Evaluates the ability of a device or material to affect healing*
- Drill defect  
*Evaluates bone healing and osteoinductive response*
- Segmental defect  
*Evaluates the ability of material(s) to stimulate/foster bone repair*
- Spinal fusion  
*Evaluates the ability of a material to fuse lumbar vertebral bodies*
- Articular cartilage repair/implant  
*Evaluates cartilage restoration*
- ACL transection  
*Evaluates osteoarthritis treatment modalities*
- Synovial joint  
*Determines efficacy (ROM) of various injectables*
- Bone implant antimicrobial efficacy  
*Determines infection reduction*

WuXi AppTec's safety and efficacy models accommodate customization to meet specific client needs.

### Product Expertise

Experienced in a variety of device/combination products and orthopedic materials, including:

- Allografts
- Biomaterials – such as collagen, HA, fibroectin, and laminen
- Cartilage
- Dematerialized bone matrix (DBM) combined with various carriers
- Growth factors
- Ortho devices – mechanical and combo products
- Stem cells
- Synthetics – polymers and ceramics

### Program Features

- Research, discovery, preclinical, and safety studies (GLP and Research)
- Model development and study design development
- Device materials evaluation and biocompatibility testing
- In-house surgeons or support for sponsor-provided surgeons
- Radiography / fluoroscopy imaging capabilities
- Animal Models:  
Mouse □ Rat □ Rabbit □ Dog □ Sheep □ Goat □ Pig
- Long-term, large-animal study capabilities
- Experienced study directors and veterinary research surgeons
- In-house histopathology services



WuXi AppTec also offers complete biocompatibility/safety and toxicology testing services.

For more information on WuXi AppTec's services please contact:

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The Leader in Combination Product Services

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